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2292 7590 11/12/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
RAGHU, GANAPATHIRAM				
ART UNIT		PAPER NUMBER		
1652				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/569,677

**Applicant(s)**

MANTYLA ET AL.

**Examiner**

GANAPATHIRAMA RAGHU

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***Application Status***

In response to the Office Action mailed on 02/13/09, applicants' response filed on 07/13/09 is acknowledged; said response amended claims 1, 13 and 21. Claims 1-23 are pending in this application and under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

***Withdrawn- Claim Rejections: 35 USC § 112, Second paragraph***

Previous rejection of claim 1 and claims 2-21 depending therefrom rejected under 35 U.S.C. 112, second paragraph, is being withdrawn due to amendments to claims.

***Withdrawn- Claim Rejections: 35 USC § 112, First paragraph***

Previous rejection of claims 1-4 and 6-21 are rejected under 35 U.S.C. 112, first paragraph, for enablement and written description, is being withdrawn due to persuasive arguments by the applicants.

***Maintained-Double Patenting rejection***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of reference patent U.S.

Patent No. 7,462,701 B2, date of patent 19/09/08. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims, because the examined claims are either anticipated by, or would have been obvious over reference claims. See, e.g., *In re Berg*, 140 F.3d 1428,46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir.1993); *In re Longi* 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-21 of the instant application are directed to a process for purification of a heterologous protein of interest, comprising providing a fusion protein comprising heterologous protein fused to a CBM intercepted by a proteolytic cleavage site, contacting said fusion protein with a functional protease fused to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest... said CBM protease is from the group of proteases consisting of enterokinase (EK)....comprising a EK catalytic (EKc) domain, said EKc encoded by a nucleic acid sequence of SEQ ID NO: 2 and said CBMs are CBM encoded by a region of the xylanase 10A gene from *Thermotoga maritima* and encoded by a sequence of SQ ID NO: 1...

Claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2 are directed to a method of production and purification a soluble from a transgenic heterologous protein of interest from a transgenic plant...., comprising providing a fusion protein comprising heterologous protein fused to a CBM intercepted by a proteolytic cleavage site,

contacting said fusion protein with a functional protease fuse to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest... said CBM protease is from the group of proteases consisting of enterokinase (EK).....comprising a EK catalytic (EKc) domain, said EKc encoded by a nucleic acid sequence of SEQ ID NO: 2 and said CBMs are CBM encoded by a region of the xylanase 10A gene from *Thermotoga maritima* and encoded by a sequence of SQ ID NO: 1. Furthermore, the preferred embodiments in the instant application and the allowed patent U.S. Patent No. 7,462,701 B2 are one and the same. The reference patent claims 1-22 therefore encompass a genus of polypeptides and encoding polynucleotides used in the process for purification of a heterologous protein of interest, which overlaps with the genus of genus of polypeptides and encoding polynucleotides used in the process for purification of a heterologous protein of interest of instant claims.

The claims 1-21 of the instant application cannot be considered patentably distinct over claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2, when there is specifically recited embodiment in the reference patent which supports the claimed method i.e., a method of production and purification a soluble from a transgenic heterologous protein of interest from a transgenic plant...., comprising providing a fusion protein comprising heterologous protein fused to a CBM intercepted by a proteolytic cleavage site, contacting said fusion protein with a functional protease fuse to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest... said CBM protease is from the group of

proteases consisting of enterokinase (EK).....comprising a EK catalytic (EKc) domain, said EKc encoded by a nucleic acid sequence of SEQ ID NO: 2 and said CBMs are CBM encoded by a region of the xylanase 10A gene from *Thermotoga maritima* and encoded by a sequence of SQ ID NO: 1, that would anticipate claims 1-21 of the instant application. Alternatively, claims 1-21 of the instant application cannot be considered patentably distinct over claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2 when there is specifically disclosed embodiment in the reference patent U.S. Patent No. 7,462,701 B2 that supports claims 1-22 of that patent and falls within the scope of the claims 1-21 herein, i. e., a process for purification of a heterologous protein of interest, comprising providing a fusion protein comprising heterologous protein fused to a CBM intercepted by a proteolytic cleavage site, contacting said fusion protein with a functional protease fused to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest... said CBM protease is from the group of proteases consisting of enterokinase (EK)....comprising a EK catalytic (EKc) domain, said EKc encoded by a nucleic acid sequence of SEQ ID NO: 2 and said CBMs are CBM encoded by a region of the xylanase 10A gene from *Thermotoga maritima* and encoded by a sequence of SQ ID NO: 1..., because it would have been obvious to one having ordinary skill in the art to modify claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2 by selecting a specifically disclosed embodiment that supports those claims of the reference patent. One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being preferred embodiment within claims 1-22 of reference patent U.S. Patent No.

7,462,701 B2.

**In support of their request that the prior rejection of claims 1-21 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2, applicants provide the following arguments: (pages 10-13 of applicants' response dated 07/13/09).**

"(i) the fusion protein in USP '701 is solely purified from transgenic plants. However, in the present invention the fusion protein is not limited to such fusion proteins. This is evidenced by the fact that the instant claims do not recite step (a) of the USP '701, i.e., disrupting the transgenic plant material; (ii) in addition, the final product of USP '701 claims the isolated fusion protein (still containing the CBM module). The present claims, on the other hand, specifically deal with the removal of CBM module from the heterologous fusion protein having a cleavage site.

**Reply:** Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

The instant application comprises a genus of methods i.e., "a process for purification of a heterologous protein of interest, comprising providing a fusion protein comprising heterologous protein fused to a CBM intercepted by a proteolytic cleavage site" and is anticipated by the USP '701. As argued by the examiner the preferred embodiments are one and the same and the specifications of the instant application and USP '701 are identical. Furthermore, claim 1 of the instant application does refer to insoluble cell-wall material and said cell wall material reads on plant cell wall material.

***Maintained-Claim Rejections 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al., (US Patent No.: 6,048,715 in IDS) in view Shani et al., (WO 00/77174 A1 in IDS). Claims 1-4 and 6-20 are directed to a process for purification of a heterologous protein of interest, comprising providing a fusion protein comprising a heterologous protein fused to any CBM from any source including variants, mutants and recombinants or any CBM encoded by any region of the xylanase 10A gene from *Thermotoga maritima* of undefined structure including variants, mutants and recombinants, said fusion protein intercepted by a proteolytic cleavage site, contacting said fusion protein with any functional protease fused to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest.

Haynes et al., disclose an aqueous phase separation system and/or purification systems, together with methods for their preparation and use, are provided which are based on polymer-ligand conjugates wherein the polymer and the composition to be separated and/or purified comprises a ligand which binds to the oligosaccharide polymer, the ligand is a polysaccharide binding peptide such as CBM which is an amino



acid sequence characterized as capable of binding to a phase-forming oligosaccharide polymer, following binding the composition may be removed from the oligosaccharide polymer or by utilizing a specific or non-specific protease that can be used for enzymatic removal of the compound from the polysaccharide binding moiety which remains bound to the oligosaccharide polymer by incorporating a protease recognition sequence between the compound and the polysaccharide binding moiety (column 3, Summary of invention; column 19, Table 6: Cellulose binding domains; column 23; column 29, Example 1; column 31, Example 6; claims columns 51-54 and entire document).

The reference of Haynes et al., although discloses an aqueous phase separation system and/or purification systems, together with methods for their preparation and use (same as the instant invention), said reference is silent regarding said fusion proteins are expressed in transgenic plants or obtained from transgenic plants (as in claims 6-20).

Shani et al., disclose a process of expressing a recombinant protein in a plant and for isolating the recombinant protein from the plant, the process is effected by (a) providing a plant, a plant derived tissue or cultured cells expressing a fusion protein including the recombinant protein and a cellulose binding peptide being fused therein, the fusion protein being compartmentalized within cells of the plant, plant derived tissue or cultured plant cells; (b) homogenizing the plant, plant derived tissue or cultured plant cells, so as to bring into contact the fusion protein with a cellulosic matter of plant, plant derived tissue or cultured plant cells, to thereby effect affinity binding of the fusion protein via the cellulose binding peptide to the cellulosic matter, thereby obtaining a

fusion protein cellulosic matter complex; and (c) isolating the fusion protein cellulosic matter complex; said reference also teaches including insertion of a protease cleavage sites in the fusion protein for releasing the heterologous protein of interest from the CBD in the fusion protein (pages 14-16).

Therefore, it would have been obvious to a person of ordinary skill in the art to combine the teachings of Haynes et al., and Shani et al., to develop a process for purification of a heterologous protein of interest, comprising providing a fusion protein comprising a heterologous protein fused to any CBM from any source including variants, mutants and recombinants or any CBM encoded by any region of the xylanase 10A gene from *Thermotoga maritima* of undefined structure including variants, mutants and recombinants, said fusion protein intercepted by a proteolytic cleavage site, contacting said fusion protein with any functional protease fused to a CBM, at conditions facilitating proteolytic cleavage by said protease, to cleave the CBM from the heterologous protein of interest. Motivation to do so derived from the combined teachings of Haynes et al., and Shani et al., that teach: (i) the advantages of fusion proteins comprising CBD binding domain and proteolytic cleavage site for ease of isolation of heterologous protein of interest and (ii) plants represent an alternative expression system for mass production of many proteins of commercial interest (Shani et al., pages 3-4). The expectation of success is high, because Haynes et al., disclose an aqueous phase separation system and/or purification systems, together with methods for their preparation and use (same as the instant invention) and Shani et al., disclose a process of expressing a recombinant protein in a plant and for isolating the

recombinant protein from the plant including recombinant fusion proteins comprising CBD and proteolytic cleavage sites.

Therefore, claims 1-4 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al., (US Patent No.: 6,048,715 in IDS) in view Shani et al., (WO 00/77174 A1 in IDS).

**In support of their request that the prior rejection of claims 1-4 and 6-20 are rejected under 35 U.S.C. 103(a), applicants provide the following arguments: (pages 15-16 of applicants' response dated 07/13/09).**

(A) Haynes et al., fails to disclose any fusion protein expressed in transgenic plants or obtained by transgenic plants... Haynes et al., does in fact, not disclose or suggest the binding of a cellulose binding module to a polysaccharide matrix, such that it can be readily released with mild, non-denaturing conditions. Haynes et al., discloses that the composition containing the PBP ligand may be removed from the oligosaccharide polymer with a removal solution having low ionic strength or containing chaotrophic agent" (Column 3, line 41-44). The only examples of such removal solutions disclosed in Haynes et al., are acid, base, urea, ethanol;, DMSO and the like (Column 26, line 16-17) and ethylene glycol (Column 31, line 65). However, these are well known denaturing agents. the present invention on the other hand, specifically requires the use of nondenaturing conditions.

**Reply (A):** Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants have completely mischaracterized the invention of Haynes et al., and are quoting select portions from Haynes et al., to support their arguments.

Examiner directs the applicants' to the following sections in Haynes et al.,:

a) See Fig . 8 Avicel fraction after binding of proteins in culture supernatants; Fig. 13A-13 B and 14, use of Avicel column for separation and purification of fusion proteins.

b) Column 3, lines 20-59: Summary of the invention: "...The ligand is a polysaccharide binding peptide (PBP) which is an amino acid sequence characterized as capable of binding to phase-forming oligosaccharide polymer.... When a protease is used, it can be provided bound to a second polysaccharide binding moiety having affinity for crystalline polysaccharide to which the first polysaccharide moiety has no affinity. Optionally, the protease can be recycled by subsequent elution from solid polysaccharide. Alternatively, the protease bound to the second polysaccharide binding moiety can be provided to a solid polysaccharide support to which the polysaccharide binding peptide does not bind..."

c) Column 8, lines 45-55: "...PBP compound bind specifically and strongly to the polymer but can be removed easily by elution with water or at high pH at ambient to physiologic temperatures...Mutant PBPs or PBDs with varying affinities for the phase-forming oligosaccharide also can be obtained to vary affinity as required for particular systems and/or applications..."

d) Column 19: Table 6 Cellulose binding domains

e) Column 21, lines 53-60: "...In general, the PBP-conjugate are bound to a phase forming oligosaccharide at neutral pH in a medium ionic strength buffer at temperatures 4 °C to at least 70 °C depending on the components of the phase separation system..."

f) Column 26, lines 7- 17: "...To separate and/or purify a component of an aqueous mixture, following partitioning of the composition comprising PBP into the oligosaccharide phase, the phases are separated and the composition comprising the PBP dissociated from the polymer phase in any variety of ways. These include contacting the separated oligosaccharide phase with a different phase-inducing polymer or salt which extracts the composition comprising the PBP; changing the chemical and/or physical condition..."

g) Column 29, Example 1: "...The clarified culture supernatant was incubated with microcrystalline cellulose (Avicel)...proteins bound tightly to the column and were removed with salt gradient (0-1N NaCl, pH 6.0), (see Fig. 7)..."

h) Columns 32-33, Example 6;

**(B) Applicants' further argue** " In Shani et al., a plant is homogenized to bring the fusion protein into contact with the cellulosic matter to form a fusion protein-cellulosic matter complex (see Shani et al., col. 8, lines 49-56). As such, the fusion protein of Shani et al., binds to and becomes a part of insoluble cellulosic matter complex... Thus, the instant invention employs a approach that is directly opposite to that of Shani et al.,..." **(page 16 of applicants' response dated 07/13/09).**

**Reply (B):** Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

For the record, the document of Shani et al., has only page numbers and no columns and therefore examiner is unable to find support in "Shani et al., col. 8, lines 49-56". Again, Applicants have completely mischaracterized the invention of Shani and examiner is unable to find support in Shani et al., for "insoluble cellulosic matter complex... and furthermore the instant claims do not recite the limitation "insoluble cellulosic matter complex""

Examiner directs the applicants' to the following sections in Shani et al.:

a) page 1, line 5-22: The present invention relates to a process of expressing and isolating recombinant proteins and recombinant protein products from plants, plant derived tissues or cultured plant cells, which process exploits (i) the high affinity between cellulose binding peptides and cellulose; (ii) the inherent abundance of cellulose in planta; and/or (iii) the simplicity associated with cellulose isolation from plants, plant derived tissue and cultured plant cells...plant homogenization, isolation of a fusion protein cellulosic matter complex and optional subsequent isolation of the fusion protein and/or the recombinant protein from complex".

b) page 9, lines 5-9 "According to further features in preferred embodiments of the invention described below, the fusion protein is compartmentalized within the cells of the plant or cultured plant cells, so as to be sequestered from cell walls of the plant or cultured plant cells".

c) pages 14-16: purification steps for recombinant fusion proteins

d) page 32: Cellulose binding peptide-recombinant protein fusions

e) pages 43-44: "...extraction can be done under conditions in which cellulose binding peptide do not bind to cellulose, for example pH higher than 10 (most CBDs) or high concentration of glucose or cellobiose (200 mM or higher) for family IX CBDs. If the initial extraction is conducted under conditions that prevent binding, the supernatant is cleared from the cellulosic matter and then the solution is brought by either dilution, dialysis or pH correction, if necessary, to a condition that enables binding, after which cellulose is added in a batch or is loaded on a cellulose column..."

Thereofre, Contrary to applicants' arguments, examiner continues to hold the following position:

i) Applicant's arguments are directed against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

ii) Moreover, the objectives of the cited references need not be the same as the instant invention to be used in an Obviousness rejection. So long as the motivation or suggestion to combine the teaching of the cited references is known or disclosed in the prior art and is obvious to one skilled in the art. This is sufficient to establish a *prima facie* case of obviousness.

iii) The instant invention is a simple combination of elements taught in the prior art, wherein the elements of prior art are combined to yield predictable results and the choice is from a finite number of identified elements with a highly predictable outcome

and expectation of success.

Examiner has endeavored in his reply above to establish that the cited references are in congruence with the obviousness rejection and teach all limitations of the instant claims i. e., meet all the criteria and parameters (Teaching, Suggestion and Motivation) as defined by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and the rationale for TSM test (Teaching, Suggestion and Motivation) according to KSR ruling.

The cited references render claims 1-4 and 6-20 *prima facie* obvious to one of ordinary skill in the art when one applies the Teaching, Suggestion and Motivation (TSM) test under the rationale for arriving at a conclusion of obviousness as suggested by the KSR ruling. The rationale applied for this rejection is as follows:

- (1) Combining prior art elements according to known method to yield predictable results.
- (2) Simple substitution of one known element for another to obtain predictable results.
- (3) "Obvious to try"- choosing from a finite number of identified, predictable solution, with a reasonable expectation of success.

Further, "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR, 550 at U.S. 398 (2007), 82 USPQ2d at 1397. All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as



claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. 398 (2007), 82 USPQ2d at 1397; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

#### ***Summary of Pending Issues***

The following is a summary of issues pending in the instant application.

1) Claims 1-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of reference patent U.S. Patent No. 7,462,701 B2, date of patent 19/09/08.

2) Claims 1-4 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haynes et al., (US Patent No.: 6,048,715 in IDS) in view Shani et al., (WO 00/77174 A1 in IDS).

#### ***Conclusion***

Claims 1-21 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the objections/rejections in each of the sections in this Office Action to be fully responsive for prosecution.

#### ***Final Comments***

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/  
Patent Examiner  
Art Unit 1652